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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,375	11/09/2001	John Tallman	99,130-J	5633

7590

01/28/2005

Steven J. Sarussi  
McDonnell Boehnen Hulbert & Berghoff  
32nd Floor  
300 S. Wacker Drive  
Chicago, IL 60606

EXAMINER
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BRANNOCK, MICHAEL T

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 01/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/045,375	<b>Applicant(s)</b> TALLMAN ET AL.	
	<b>Examiner</b> Michael Brannock	<b>Art Unit</b> 1646	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 1-35 and 48-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 36-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>100101</u> . | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1646

***Status of Application: Claims and Amendments***

Claims 1-36 and 48-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/8/04.

The traversal is on the grounds that a search of Groups IV and VII would not be a serious burden on the examiner. This is not found persuasive for the following reasons:

Under MPEP § 803, there are two criteria for a proper requirement for restriction between patentably distinct inventions:

(A) The inventions must be independent (see MPEP § 8702.01, 806.04, 808.01) or distinct as claimed (see MPEP § 806.05- §806.05(I)): and

(B) There must be a serious burden on the examiner if restriction is required (see MPEP § 803.02, § 806.04(a)- 806.04(I), § 808.01(a), and § 808.02).

Consistent with current patent practice, a serious search burden may be established by (A) separate classification thereof: (B) a separate status in the art when they are classifiable together: (C) a different field of search. These criteria were met in the above restriction. Therefore, the restriction is maintained and made Final

***Priority***

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific

Art Unit: 1646

reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24-35 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S.

Patent No: 6444666 filed 8/27/05.

The invention of the instant claims is predicated on the idea that selective activation GABA  $\alpha 2\beta\gamma 2$  or  $\alpha 2\beta\gamma 2$  receptors, while minimizing activation of receptors having  $\alpha 1$  subtype, will produce antidepressive effects with minimal sedative and cognitive impairing effects, see pages 33-39.

Patent No: 6444666 teach this principle with regard to anxiety and depression, see the see col 2, lines 10-26, and particularly lines 37-38. *In vivo* confirmation of the response sensitivity, e.g. claims 46 and 47, is also taught, see col 9, lines 1-5. These teaching differs from the instant claims in several insignificant ways. U.S. Patent No: 6444666 does not teach any particular  $EC_{50}$ , e.g. that the  $EC_{50}$  be less than 200 nM as in the instant claim 37. One of ordinary skill in the art of pharmacology would not need to

Art Unit: 1646

be taught a particular number to use as this would readily be apparent during routine optimization of operating parameters.

Claims 24-35 rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen-L, et al., WO 98/19165 in view of the Abstract of Calogero-AE et al, Brain Res 463(1)28-36, 1988.

The invention of the instant claims is predicated on the idea that selective activation GABA  $\alpha 2\beta 3\gamma 2$  receptors, while minimizing activation of receptors having  $\alpha 1$  subtype, will produce antidepressant effects with minimal sedative and cognitive impairing effects, see pages 33-39.

Jensen-L, et al. teach this principle with regard to anxiety, see the Abstract and also teach an assay that measures the in vitro efficacy of a compound and the affinity of the compound on  $\alpha 2\beta 3\gamma 2$  receptors and comparing these parameters of the compound toward receptors having the  $\alpha 1$  subtype, and choosing the compound that is selective for the  $\alpha 2\beta 3\gamma 2$  receptor, see claim 8. This claim differs from the instant claims in several insignificant ways. First, it is recognized in the art that anxiety and depression are distinct entities, yet it is also well appreciated that the two disorders demonstrate substantial overlap with regard to the drugs useful for their treatment, see the Abstract of Calogero for example. Second, Jensen does not teach any particular  $EC_{50}$ , e.g. that the  $EC_{50}$  be less than 200 nM as in the instant claim 24. One of ordinary skill in the art of pharmacology would not need to be taught a particular number to use as this would readily be apparent during routine optimization of operating parameters. Further, claims

Art Unit: 1646

46 and 47 require the additional steps of measuring the selectivity *in vivo* and Jensen do not discuss this. However, as the object of the assay of Jensen is to identify agents that would be useful for *in vivo* use, it would be obvious to one of ordinary skill in the art to additionally measure the *in vivo* efficacy using the old and well established models of anxiety and sedation.

Therefore it would be obvious to one of ordinary skill in the art, at the time the invention was made, and with reasonable expectation of success to screen for compounds exhibiting antidepressive activity, as suggested by Calogero, using the selective activation GABA  $\alpha 2\beta 3\gamma 2$  receptors as opposed to  $\alpha 1$  subtype receptors. The motivation to do so being provided by Calogero who teach the antidepressive and anxiolytic properties of drugs that act through GABA<sub>A</sub>.

Art Unit: 1646

*Conclusion*

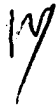
Please note the new central fax number for official correspondence below:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

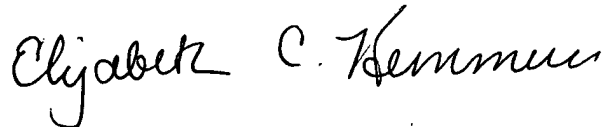
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached at (571) 272-0829. Official papers filed by fax should be directed to 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB



January 23, 2005



ELIZABETH C. KEMMER  
FAXED 1/23/05